03-SAR-051

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Centers for Disease Control and Prevention
National Center for Infectious Diseases
Select Agent Transfer Program
1600 Clifton Road NE.
Mailstop E-79
Atlanta, Georgia 30333

Docket No. 02-088-1
Regulatory Analysis and Development
PPD, APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, Maryland 20737-1238.

RE: CDC Final Interim Rules for 42 CFR Part 73 and 42 CFR Part 1003; USDA Docket No. 02-088-1,

Dear Sirs,

In response to your request for comments regarding the Interim Final Rules of December 10, 2002 I would like to offer the following.

Paragraphs 73.11, 331.11 and 121.12. I recommend the Final Rules clearly distinguish between laboratory security and entity security.

In large academic settings it is possible for a fully secure laboratory facility to coexist with a functioning educational and research laboratory entity. Placing full security restrictions on a building primarily devoted to educational functions compromises an educational institution's ability to fulfill its primary functions. This, in turn, may force laboratories working with select agents to shut their biodefense studies or move elsewhere.

Paragraphs 73.6 (b) and 121.4 (c). I recommend the conflict between these two paragraphs in their restrictions on the use of cleared, approved, licensed or registered agents be resolved in favor of paragraph 121.3(c).

Paragraph 73.6 (b) restricts the use of these agents (including overlap agents) to ". . . their use is only for the approved purpose . . .", while paragraph 121.4(c), which covers overlap agents, makes no such restriction

Paragraphs 73.6 (b) and 121.4 (c). I recommend CDC and APHIS provide a listing of exempt biological agents according to (1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); (2) Section 351 of Public Health Service Act (42 U.S.C. 262); (3) The Virus-Serum-Toxin Act (21 U.S.C. 151-159); or (4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 et seq.).

Efforts to obtain these lists from the appropriate agencies have proved to be unsuccessful. Investigators would benefit greatly from knowing whether the agents they possess or wish to study are exempt.

Paragraphs 73.6 (b) and 121.4 (c). I recommend the Final Rules exempt microorganisms cleared, approved, licensed or registered by the USDA for veterinary uses.

I greatly appreciate the opportunity to comment on the Interim Final Rules.

Sincerely yours,

Andrew G. Braun, Sc.D.

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Coordinator, Harvard Committee on Microbiological Safety
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